

B 9 1/2 24. **(Twice amended)** An electromagnetic radiation therapy system according to Claim 21 wherein the means for emitting includes a PN junction arranged to emit radiation with a wavelength centring at, or about, 1072nm or at, or about, 1268 nm.

25. **(Amended)** An electromagnetic radiation therapy system according to Claim 24 comprising a single light diode assembly including a plurality of orientated junctions.

B 10 26. **(Amended)** An electromagnetic radiation therapy system according to Claim 22 wherein the gas discharge device may include a mixture of gases which will give an output at the desired wavelength centered at, or about, 1072 nm or 1268 nm.

Please delete Claims 27-30.

REMARKS

Applicant hereby requests further consideration of the application in view of the amendments above and the comments that follow.

Objection to the Drawings

Applicant submits herewith a Request for Approval of Proposed Changes to the Drawings including marked up drawings. Applicant respectfully submits that the objections to the drawings are overcome by the proposed drawing revisions. Applicant respectfully submits that the claimed inventions are fully and accurately disclosed in the specification as filed, but provides the following comments and appendices to facilitate the Examiner's review of the application.

For the Examiner's reference, Applicant submits herewith as **Appendix A** an annotated copy of Figure 1 wherein exemplary electronics that may be used in an electromagnetic therapy system of the present invention are shown mounted in the

hollow 3. In the illustrated electronics, R = resistor, T = transistor, VR = variable resistor, MOSFET = metal oxide semiconductor field effect transistor, and PIC = programmable integrated circuit. Applicant also submits herewith as **Appendix B** a diagram of an exemplary circuit that may be used in an electromagnetic therapy system of the present invention. Other suitable circuits will be readily apparent to those skilled in the art upon review of Applicant's disclosure.

Regarding loop 6, Figure 1 is a plan view with the cover removed and Figure 3 is an underside plan view. Loop 6 is correctly positioned in each figure if Figure 1 is rotated 90 degrees to the right and viewed from below.

Regarding the use of the side shield to exclude ambient light, the side shield may match the body part to which it is applied or may be flexible to generally conform to the to the shape of the body part.

Objection to the Specification

Applicant respectfully submits that the objections to the specification are overcome by the foregoing amendments to the specification and the proposed drawing revisions.

Regarding the objection to Claim 17, Applicant directs the Examiner's attention to page 5, lines 16-21 and page 9, lines 11-12 of the specification.

Status of the Claims

Claims 1-30 are pending in the application. Claims 1-4, 6-12, 15-24 and 27-30 stand rejected under Section 102 as being anticipated by U.S. Patent No. 6,063,108 to Salansky et al. (hereinafter "Salansky"). Claim 5 stands rejected under Section 103 as being unpatentable over Salansky. Claims 13 and 14 stand rejected under Section 103 as being unpatentable over Salansky. Claim 26 stands rejected under Section 103 as being unpatentable over Salansky in view of U.S. patent No. 5,527,350 to Grove et al. (hereinafter "Grove '350"). Claim 25 stands rejected under Section 103 as being unpatentable over Salansky in view of *Lasers and Electro-Optics* by Christopher C. Davis (hereinafter "Davis").

The Rejections under Sections 102 and 103

Claims 1-4, 6-12, 15-24 and 27-30 stand rejected under Section 102 as being anticipated by Salansky. Claim 5 stands rejected under Section 103 as being unpatentable over Salansky. Claims 13 and 14 stand rejected under Section 103 as being unpatentable over Salansky. All of the pending claims depend from Claim 1 as amended. As discussed in more detail below, Salansky fails to anticipate or render obvious Claim 1 as amended.

Claim 1 as amended recites:

1. An electromagnetic radiation therapy system comprising means for emitting narrow band divergent electromagnetic radiation at a wavelength centered at, or about, 1072nm and/or at a wavelength centered at, or about, 1268nm, the system being capable of producing, at the site being treated, a radiation intensity of at least 50 $\mu\text{Watts/cm}^2$ and up to 2 Watts/cm^2 .

For the Examiner's reference, Applicant submits herewith as **Appendix C** an article by the inventor entitled *A pilot study of treatment of herpes labialis with 1072 nm narrow waveband light* from *Clinical and Experimental Dermatology*, 26, 149-154. The article reports results from an exemplary system employing means for emitting narrow band divergent electromagnetic radiation at a wavelength of 1072 nm. The article confirms the surprising observation of the effectiveness of narrow band divergent electromagnetic radiation at a wavelength centered at, or about, 1072 nm hitherto not considered for herpes therapy and proposes that the effect is as a result of altered cell membrane permeability and the peak transmission of water molecules at 1072nm. Thus, this document further demonstrates the effectiveness of embodiments of the claimed invention and the non-obviousness of the invention as claimed.

Salansky discloses a beam of light of wavelength 400 to 2,000nm (column 3, line 44) and preferred embodiments of range of light of from 630 to 700 nm, from 740 to 760nm, or from 800 to 1100nm (claim 1). The intensity is specified as 0.2 to 5,000 mW/cm^2 ; however, with regard to the 800 to 1100nm wavelength range, the intensity

ranges disclosed are from 10 to 40 mW/cm² to 60 to 100 mW/cm² or 300 to 600 mW/cm² or 1000 to 5000 mW/cm².

Salansky does not expressly specify the 1072 or 1268nm wavelengths of the present invention. Moreover, Salansky does not recognize the surprising effects of these wavelengths *vis a vis* water molecule transmission peaks. *See, e.g.*, Applicant's specification at page 2, lines 19 to 23, and the article by the inventor discussed above and submitted herewith as **Appendix C**. For example, for the treatment of herpes and acne, Salansky uses 600-700nm light, not 1072 or 1268nm as per the claimed invention.

Moreover, Salansky in effect teaches away from the claimed invention. While Salansky does specify superluminous or light emitting diodes (column 3, line 51), Salansky has excluded the standard infrared LED with the statement "The full bandwidth of the monochromatic light to activate the healing phenomenon should not exceed 30-40nm" (column 16, lines 42-43, column 41, claim 1d, claim 3; emphasis added). Standard infrared LEDs (light emitting diodes) have an inherent total bandwidth of 100-120nm. Visible LEDs can have a reduced bandwidth of 30-40nm (*see, e.g.*, the graph from *Optoelectronics Handbook* submitted herewith as **Appendix D**). The device of the present invention employs infrared LEDs centered at approximately 1072nm or 1268nm with a total bandwidth of approximately 120nm, *i.e.*, a device Salansky specifically excludes. Salansky states that it is desired to avoid wider ranges of wavelengths (column 16, lines 28-31) – in effect Salansky has restricted the device to the use of laser sources in the infrared range. At column 18, lines 13-15, Salansky further defines the LEDs employed as being in the visible spectrum (red). To the skilled artisan, "full bandwidth" means 90% of the optical power must be within 30-40nm bandwidth. This should be differentiated from the "spectral bandwidth" specified by the LED manufacturer, which is the bandwidth in which 50% of the optical power is emitted. As regards the physics involved in manufacturing a LED, with present technology it is not commercially viable (and may not even be possible) to produce a 1072nm LED with a full bandwidth of only 30-40nm. At present, only devices employing lasers can give a narrow bandwidth in the

IR range. Salansky therefore necessarily excludes a device employing a standard infrared LED as the means for emitting narrow band divergent electromagnetic radiation centered at or about 1072nm and/or 1268nm since the total band width is approximately 120nm, that is, outside the range of no more than 30-40nm as specified in Salansky (column 16, line 43).

The 1072nm transmission peak of the water molecule has a full bandwidth almost identical to a standard IR LED. By specifying this as the spectral output of the device of the present invention, the device employs a distinctly different light source excluded by the Salansky prior art. Moreover, neither Salansky nor any other of the cited references specifically mentions the wavelengths of the claimed invention or their coincidence with the water transmission peaks.

Applicant further notes that the minimum intensity range for the 800 to 1100nm wavelength range in Salansky is given as 10 mW/cm^2 , whereas the intensity used in the present invention to treat herpes/cold sores is 5 to 10 mW/cm^2 , *i.e.*, values below that of Salansky. Also, the minimum dose of photons necessary for the cold sore device of the present invention is $180 \text{ sec} \times 600 \times 0.00001 \text{ secs} \times 0.01 \text{ W} = 0.011 \text{ J/sq cm}$, *i.e.*, one order of magnitude below Salansky's minimum. These points serve as further evidence of Salansky's failure to recognize the special effects of narrow band divergent electromagnetic radiation centered at or about 1072nm and/or 1268nm and an appropriate dosing regimen for herpes/cold sore treatment.

In view of the foregoing, Applicant respectfully submits that Claim 1 as amended is clearly allowable over the cited art. Claims 2-26 depend from Claim 1 as amended and are therefore allowable as well for at least the foregoing reasons.

Claim 26 stands rejected under Section 103 as being unpatentable over Salansky in view of Grove '350. Grove '350 is cited as teaching the use of gas lasers in tissue treatment. However, Grove '350 in no way satisfies the deficiencies of Salansky as discussed above with regard Claim 1, from which Claim 26 depends.

Claim 25 stands rejected under Section 103 as being unpatentable over Salansky in view of Davis. Davis is cited as teaching the use of a diode with multiple

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PN junctions. However, Davis in no way satisfies the deficiencies of Salansky as discussed above with regard Claim 1, from which Claim 25 depends.

CONCLUSION

Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

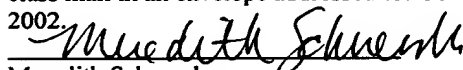


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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on May 30, 2002.


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